



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

JUL 5 2005

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Melanie Fairchild-Dzani  
Director, Regulatory Issues – Special Nutritionals  
Nestlé USA  
Nutrition Division  
800 North Brand Boulevard  
Glendale, CA 91203

RE: Qualified Health Claim Petition – 100% Whey Protein Partially Hydrolyzed in Infant  
Formula and Reducing the Risk of Allergy in Infants

Dear Ms. Fairchild-Dzani:

This letter acknowledges receipt on June 20, 2005 by the Food and Drug Administration (FDA) of the petition you submitted, on behalf of Nestlé USA (Nestlé), pursuant to Section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 343(r)(4)) and in accordance with the July 10, 2003 Task Force Final Report on the Consumer Health Information for Better Nutrition Initiative. The petition requests a qualified health claim for the relationship between the consumption of 100% whey protein partially hydrolyzed in infant formula and a reduction in the risk of allergy in infants.

The petition is undergoing initial FDA review. In accordance with interim procedures set forth in the aforementioned Task Force Final Report (<http://www.cfsan.fda.gov/~dms/nutftoc.html>), within 45 days of receipt of your petition, you will be notified of FDA's decision to either file the petition for comprehensive review, or to deny the petition. A denial may be by either FDA action within the initial 45-day period, which ends on August 4, 2005, or by a lack of action by FDA within the initial 45-day period, in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

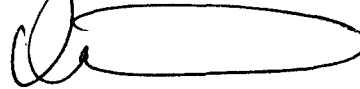
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ACK 1

Page 2 - Melanie Fairchild-Dzanis

Please feel free to contact me at 301-436-1450 if you have any questions concerning this petition.

Sincerely yours,

A handwritten signature in black ink, consisting of a stylized 'V' followed by a horizontal oval shape.

Vincent de Jesus, M.S., R.D.  
Nutrition Programs and Labeling Staff  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition